

Appl. No.: 10/030,974
Group Art Unit: 1623
Applicants' Reply to the Office Action mailed March 17, 2004

REMARKS

Claims 19-38 are currently pending in the present application.

Claims 19 and 31 have been amended to specify that the precipitant is added such that a crosslinker-free chitosan composition having physically entangled strands of the chitosan is formed. Support for the amendments to claims 19 and 31 can be found in the Specification, for example, at page 4, lines 3-9. No new matter has been introduced. Applicants submit that no fees for additional claims are due. A complete listing of all claims ever presented is included herein in accordance with 37 C.F.R. §1.121(c). Entry of the amendments is therefore proper and respectfully requested.

In the Office Action, the Examiner rejects claims 19-23, 25, 26 and 29-37 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-25 and 28-37 of copending U.S. patent application number 10/030,933 (hereinafter referred to as "the copending application"). The Examiner contends that although the conflicting claims are not identical, they are not patentably distinct from each other. Specifically, the Examiner contends that the claims of the instant application are drawn to a process for preparing a crosslinker-free composition comprising: providing an aqueous mixture of chitosan, combining a precipitant with the aqueous mixture to form a crosslinker-free composition and drying to form a three-dimensional structure. The Examiner further contends that the claims of the copending application recite the same limitations except that the claims are drawn to a biopolymer. On this basis the Examiner argues that there is no patentable distinction between the claims.

Applicants respectfully traverse the Examiner's rejection, and the contentions and arguments in support thereof, for the following reasons. To begin with, Applicants submit that the Examiner's assessment of the claims of the copending application is incorrect. Applicants would like to point out that the claims of the copending application were amended on February 10, 2004, such that the claims are now directed to a process for preparing a crosslinker-free composition, wherein the process comprises: (a) providing an aqueous mixture of a polysaccharide biopolymer; (b) combining a precipitant with the aqueous mixture; and (c) dewatering the cross-linker-free biopolymer composition to form a crosslinker-free three-

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dimensional structure. Secondly, applicants submit that the claims of the instant application and the claims of the copending application, as amended on February 10, 2004, are patentable to distinct.

Applicants respectfully submit that the claims of the copending application which specify the provision of a *polysaccharide* biopolymer do not obviate the claims of the instant application. The chitosans recited in the claims of the instant application, as explained in the Specification beginning at page 4, line 17, are biopolymers which belong to the group of hydrocolloids. Chemically, they are partly deacylated chitins, differing in their molecular weights, which contain an aminated monomer, as shown on page 4 of the Specification. The polysaccharide biopolymers of the copending application, such as cellulose, pectins, alginates, carageenes, agar-agar, and derivatives thereof, are different.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of claims 19-23, 25, 26 and 29-37, under the judicially created doctrine of obviousness-type double patenting.

In the Office Action, the Examiner maintains the rejection of claims 19-23, 25-28, 32-35 and 37-38 under 35 U.S.C. §102(b), as being anticipated by Japanese Patent Publication No. JP 01-062302 A (hereinafter referred to as "JP '302"). In addition, the Examiner specifically withdraws the previous indication of allowability for claims 24, 31 and 36 and rejects these claims under 35 U.S.C. §102(b), as being anticipated by JP '302. Applicants would like to note that two full English translations of JP '302 have been made of record in the instant application. In an Information Disclosure Statement filed by Applicants on November 20, 2003, a full English translation of JP '302 was filed, and in addition, the Examiner attached to the Office action, a full English translation of JP '302 along with a Form PTO-892 citing the translation. Hereinafter, all references to JP '302 are to the full English translation of the Japanese document as cited by the Examiner.

Specifically, the Examiner contends that "[t]he instant claims are drawn to a process for preparing a cross-linker free composition comprising an aqueous mixture of chitosan and combining a precipitant with the aqueous mixture to form a cross-linker free chitosan

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composition and drying the composition to form a three-dimensional structure." (*See*, the Office Action, p.4). The Examiner argues that JP '302 "teaches the same process steps", and thus JP '302 "is seen to produce a cross-linker free three-dimensional chitosan product." (*See, id.*). The Examiner also contends that Applicants' argument that JP '302 discloses the slow neutralization of the acidic chitosan solution to prepare a neutralized *solution* of the chitosan salt, as opposed to the precipitation of entangled, three-dimensional, physically cross-linked chitosan products, is not persuasive. On these bases, the Examiner argues that the claimed invention is anticipated and maintains the rejection.

Applicants strenuously, but respectfully, traverse the Examiner's rejection and the arguments and contentions in support thereof for the following reasons.

To begin with, in order for a rejection under 35 U.S.C. §102 to be proper, each and every element of the claimed invention must be taught, either expressly or inherently, in a single prior art reference. (*See, e.g., M.P.E.P. §2131*). Applicants submit that JP '302 fails to teach each and every element of the claimed invention.

Applicants' claimed invention, as amended herein, is directed to processes for preparing a crosslinker-free composition, comprising: (a) providing an aqueous mixture of a chitosan, wherein the aqueous mixture has a viscosity of from 1,000 mPas to 100,000 mPas; (b) combining a precipitant with the aqueous mixture *in an amount and at a rate sufficient to precipitate the chitosan such that a crosslinker-free chitosan composition having physically entangled strands of the chitosan is formed*; and (c) drying the crosslinker-free chitosan composition to form a crosslinker-free three-dimensional structure.

JP '302 is directed to the production of a **water-soluble chitosan salt**. The water-soluble powders of the reference are different from the physically entangled chitosan that forms the three dimensional structures of the present invention. JP '302 teaches the slow neutralization of the acidic solution to prepare a neutralized **solution** of the water-soluble chitosan salt. (*See, English Trans. of JP '302, p. 3, 3rd ¶*). JP '302 is not directed to the production of entangled, three-dimensional, "physically cross-linked" chitosan products, as claimed.

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Applicants' claimed invention is directed to the production of cross-linker free, three-dimensional structures. As described in the Specification, the precipitant is added quickly so as to cause the entanglement and physical "crosslinking" of the chitosan. (See, Applicants' Spec., pp. 9-10).

Applicants respectfully submit that JP '302 fails to teach a process for preparing a cross-linker free, three-dimensional structure, as claimed. Accordingly, JP '302 fails to anticipate the claimed invention. Thus, reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. §102 based on JP '302 are respectfully requested.

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance are respectfully requested.

Respectfully submitted,

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